Missouri Department of Health and Senior Services Recall Alert

The Missouri Department of Health and Senior Services received the following recall regarding TYLENOL® 8 Hour Extended Release Caplets 150 count bottles. The product was distributed nationwide.

MCNEIL CONSUMER HEALTHCARE ANNOUNCES VOLUNTARY RECALL OF CERTAIN OTC PRODUCTS

March 29, 2011- Fort Washington, PA – McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling one product lot of TYLENOL® 8 Hour Extended Release Caplets 150 count bottles distributed in the United States. McNeil is taking this action as part of our ongoing surveillance and monitoring efforts that identified a small number of complaints of a musty or moldy odor. The uncharacteristic odor is thought to be caused by the presence of trace amounts of chemicals called 2,4,6-tribromoanisole (TBA) and 2,4,6-trichloroanisole (TCA). This voluntary action is being taken as a precaution and the risk of adverse medical events is remote. The product was manufactured at the McNeil Consumer Healthcare plant in Fort Washington, PA prior to the company's voluntary closure of the facility in April 2010.

The lot number for the recalled product can be found on the side of the bottle label.

FULL RECALLED PRODUCT LIST:

Product Name	Lot Number	UPC Code
TYLENOL® 8 HOUR EXTENDED RELEASE CAPLET 150 count	ADM074	300450297181

Consumers who purchased product from the lot included in this recall should stop using the product and contact McNeil Consumer Healthcare, either at www.tylenol.com or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time) for instructions about receiving a refund or product coupon. Consumers who have medical concerns or questions should contact their healthcare provider.

Any adverse reactions may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Separately, McNeil Consumer Healthcare is also adding ten lots of other products to a wholesale level recall it initiated on January 14th, 2011. That recall did not require any action by consumers or healthcare providers and was not undertaken on the basis of adverse events. More information about this wholesale level recall is available at www.mcneilproductrecall.com.

These recalls are being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).